UNITED STATES OF AMERICA BEFORE THE FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

)) FDA	A DOCKET: 00N-1571
In the Matter of:)	
Enrofloxacin for Poultry: Withdrawal)	
of Approval of Bayer Corporation's)	
New Animal Drug Application)	
(NADA) 140-828 (Baytril))	
)	
)	

On July 3, 2003 Respondent Bayer Corporation made a request for clarification of the May 9, 2003 Notice and Order, particularly the provision ordering the parties to submit "initial concurrent briefs not to exceed 100 pages." Specifically, Bayer sought clarification of whether the regulation requirement that briefs must "contain proposed findings of fact and conclusions of law" (21 C.F.R. 12.96(a)) requires them to be included within the brief or whether they may be included in a separate document submitted concurrently, and merely cited to in the briefs.

There is no ambiguity in the Notice and Order issued in May—May 9, 2003.

Accordingly, no clarification is necessary.

DATED this day of July, 2003.

/s/ Daniel J. Davidson
Daniel J. Davidson
Administrative Law Judge

2000N-1571